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10/691,928	10/23/2003	Jay A. Goldstein	JAG 100	1611

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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/691,928	GOLDSTEIN ET AL.	
	Examiner	Art Unit	
	Nathan W. Schlientz	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/3/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Claims 1-17 are pending in the present application and are examined herein on the merits for patentability. No claim is allowed at this time.

Withdrawn Rejections

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

1. Claims 1 and 8-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Quigley et al. (US 6,075,056).

Quigley et al. disclose a lotion having the following composition: water, the solvent propylene glycol, the humectant glycerin, the emulsifier glyceryl monostrearate, the preservatives benzyl alcohol and sodium benzoate, the base triethanolamine, a

steroid from about 0.01 to 0.1 wt.%, preferably betamethasone dipropionate (betamethasone dipropionate lotion is a class 5 lower-mid strength potency steroid at 0.02 wt.%, see column 5, line 31), and the antifungal butenafine HCl (column 11, lines 3-23; Table G). Quigley et al. also discloses the antifungal compounds include terbinafine and naftifine (column 4, lines 4-51). Quigley et al. further disclose that steroids that penetrate the skin cause undesirable side effects (column 1, lines 28-29), and penetration of the epidermis with the test formulations proved to be significantly lower than that shown for Lotrisone formulation (column 18, lines 38-42). Therefore, Quigley et al. disclose a lotion composition comprising all the limitations of the instant claims and discloses the desire to minimize penetration of the steroid through the epidermis in an attempt to avoid undesirable side effects. Although the composition listed in Table G of Quigley et al. discloses butenafine as the preferred antifungal, the disclosure recites three antifungal agents of particular interest: terbinafine, naftifine and butenafine (col. 3, l. 63 - col. 4, l. 51). Therefore, one of ordinary skill in the art would immediately envisage a composition comprising all the ingredients listed in Table G, except substituting terbinafine or naftifine for butenafine.

Response to Arguments

Applicants argue on pages 4-6 that the examples of Quigley et al. use steroidal anti-inflammatories that are more potent than low to low-medium potency (Ex. 10 and 12). Applicants further argue that based on the teachings of Quigley et al., one would expect to see lower efficacy for the formulations comprising low potency steroidal anti-inflammatories and greater efficacy for the formulations comprising higher potency

steroidal anti-inflammatories. Applicants argue that Quigley et al. clearly teach away from selecting a steroidal anti-inflammatory that is low to low-medium potency in order to avoid local side effects.

However, the examiner respectfully argues that Table G of Quigley et al. clearly discloses lotion formulations that comprise from 0.01 to 0.1 wt.% steroid and 1 to 3 wt.% antifungal with a pH of 3.5 to 7.0, wherein the preferred steroid is betamethasone dipropionate. Betamethasone dipropionate in a lotion at 0.02 wt.% or less is a class 5 (low-medium) potency steroid according to the table on col. 4-5. Also, Quigley et al. claim a cream comprising 0.001 to 2.5 wt.% steroidal anti-inflammatory, wherein the steroid is selected from betamethasone, betamethasone dipropionate, fluocinonide, fluocinoline acetonide, hydrocortisone, methylprednisolone, clobetasol, and beclomethasone (Claims 1-7). Fluocinolone acetonide is a low-medium potency steroid as a cream at 0.025 wt.%, hydrocortisone is a low potency steroid at 2.5 wt.%, and methylprednisolone is a low potency steroid at 1 wt.%, according to the table on col. 4-5. Therefore, Quigley et al. clearly envisaged a composition comprising an antifungal and a steroidal anti-inflammatory where the steroidal anti-inflammatory is a low to low-medium potency steroid.

Also, the examiner directs attention to MPEP 2123(I) and (II):

> A reference may be relied upon for all that it would have reasonably suggested to one having ordinary skill the art, including nonpreferred embodiments. *Merck & Co. v. Biocraft Laboratories*, 874 F.2d 804, 10 USPQ2d 1843 (Fed. Cir.), cert. denied, 493 U.S. 975 (1989). See also *Upsher-Smith Labs. v. Pamlab, LLC*, 412 F.3d 1319, 1323, 75 USPQ2d 1213, 1215 (Fed. Cir. 2005); *Celeritas Technologies Ltd. v. Rockwell International Corp.*, 150 F.3d 1354, 1361, 47 USPQ2d 1516, 1522-23 (Fed. Cir. 1998) (The court held that the prior art anticipated the claims even though it taught away from the claimed

invention. "The fact that a modem with a single carrier data signal is shown to be less than optimal does not vitiate the fact that it is disclosed.").

Disclosed examples and preferred embodiments do not constitute a teaching away from a broader disclosure or nonpreferred embodiments. *In re Susi,* 440 F.2d 442, 169 USPQ 423 (CCPA 1971). "A known or obvious composition does not become patentable simply because it has been described as somewhat inferior to some other product for the same use." *In re Gurley*, 27 F.3d 551, 554, 31 USPQ2d 1130, 1132 (Fed. Cir. 1994). Furthermore, "[t]he prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed...." *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004).

Quigley et al. do not criticize, discredit, or otherwise discourage the use of low to low-medium potency steroids in the formulations. In fact, Quigley et al. do the opposite by stating on col. 4, ln. 52-54, "The topical compositions of the present invention include anti-inflammatory steroids. Such steroids *are exemplified in, but not limited to, the following table*", wherein Quigley et al. disclose a table comprising low to low-medium potency steroids; as well as by claiming compositions comprising 0.001 to 2.5 wt.% steroidal anti-inflammatory including fluocinolone acetonide, hydrocortisone and methylprednisolone. Therefore, Quigley et al. clearly teach that the low to low-medium potency steroids are suitable for use in their invention.

2. Claims 1-3, 8-13 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Burnett et al. (US 6,238,683, published 29 May 2001, same disclosure as EP 1 159 956).

Burnett et al. disclose compositions comprising an antifungal (i.e. ketoconazole and like related imidazole antifungal agents), a steroidal anti-inflammatory (i.e. desonide), a solvent/penetration enhancer (i.e. propylene glycol), a humectant (i.e.

glycerin and/or sorbitol), an emollient (stearyl alcohol or cetyl alcohol), dibasic sodium phosphate, PPG-15 stearyl ether, and benzoic acid (abstract; col. 1, ll. 14-22; col. 2, ll. 5-29 and 47-67; col. 3, ll. 1-60; and Tables 1-4). Burnett et al. further disclose that topical compositions known in the prior art comprise an antifungal and steroid have a pH of between 2.5 and 6 (col. 1, ll. 54-58). Burnett et al. further disclose treating *Trichophyton rubrum* (i.e. tinea corporis, tinea cruris and tinea pedis) with the compositions of their invention (col. 7, ll. 14-23).

It is noted that Burnett et al. disclose the required penetration enhancer/solvent selected from the group consisting of alcohol, propylene glycol, or a combination thereof (col. 2, ll. 47-56), wherein the instant invention requires the composition does not cause the steroids to penetrate the skin and cause undesirable side effects (instant claim 1). However, propylene glycol is a solvent listed in the instant claim 12. Also, Burnett et al. disclose that the compositions of their invention demonstrate targeted delivery of desonide to the skin (cutaneous compartments) with greater amounts of the medicaments in the intended sites of the epidermis and dermis (col. 8, ll. 29-44). Burnett et al. state that the compositions demonstrated positively less permeation through the skin into the receptor that could clinically translate into lower systemic toxicity (col. 8, ll. 45-59). Therefore, even though Burnett et al. refer to the solvent propylene glycol (same as instantly claimed) as a penetration enhancer/solvent, they clarify the desire to prevent permeation of the medicament through the skin and into the receptor, resulting in diminished side effects. Thus, the compositions of Burnett et al. are disclosed not to penetrate through the skin and into the receptor.

Response to Arguments

Applicant's arguments with respect to EP 1 159 956 are addressed here under US 6,238,683 because the disclosures are the same. Applicants argue on pages 6-7 that the compositions of Burnett et al. require the use of a penetration enhancer which causes penetration into the dermis, leading to higher potency and local side effects.

However, the examiner respectfully argues that Burnett discloses a composition comprising 2 wt.% ketoconazole and 0.05 wt.% desonide in propylene glycol, PEG, glycerin, PPG-15 stearyl ether, hydroxypropyl cellulose, ascorbic acid, citric acid, BHT and ethanol (Table 1 and Table 9 Example 6). Desonide cream at 0.05 wt.% is a low potency steroid. Burnett discloses that the compositions of Example 1 (Table 1) demonstrated targeted delivery to the epidermis and dermis with less to the receptor, which may translate to lower systemic absorption and lower systemic toxicity (col. 8, ln. 29-58). The instant specification states that steroids can penetrate the skin and cause undesirable side effects, but the specification does not define the different layers of the skin and at which layer the side effects occur if penetrated.

Also, Burnett et al. teach that the penetration enhancer includes an alcohol, such as ethanol, or propylene glycol present from 1-50 wt.%. The instant specification states that solvents, such as alcohols (i.e. ethanol) and propylene glycol are incorporated at up to 40 wt.%, more preferably about 5-30 wt.%. Instant claim 12 states that the solvent can be propylene glycol. Therefore, the instantly claimed composition comprises the same penetration enhancer/solvent as disclosed by Burnett et al. Also, instant claim 12 lists emollients, humectants, emulsifiers, acids, bases, buffering agents, and

preservatives that can be included in the composition of the instant invention. Burnett et al. teach their compositions comprising a humectant, such as PEG, glycerin and sorbitol; emollients, such as ; pH adjusters, such as malic acid, lactic acid, citric acid, glycolic acid, benzoic acid and ascorbic acid; and antioxidants. Thus, many of the same components disclosed in Burnett et al. are also present in the instant compositions.

It is also noted that claim 1 states that the composition does not cause the steroids to penetrate the skin and cause *undesirable* local side effects. Therefore, the composition could potentially penetrate the skin so long as there are no *undesirable* local side effects. Also, *undesirable* local side effects is subjective depending on the interpreter of the claim. The instant claims do not define what local side effects are to be avoided, and what is considered undesirable. If the composition treats the fungal infection, minor side effects may not be objectionable.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in Graham v. John Deere Co., 383 U.S. 1,148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.

2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 1-3 and 7-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Quigley et al. (US 6,075,056) as evidenced by the instant specification.

Applicant's claims

Applicant claims a topical antifungal composition comprising an antifungal, a low to low-medium potency non-halogenated steroidal anti-inflammatory (listed in claim 7), and a carrier that does not afford penetration of the steroid through the skin causing undesirable side effects. Applicant further claims a method of treating a fungal disease (listed in claim 16) comprising administering the aforementioned composition with a thin application of the composition two times per day to the affected areas, wherein the patient may comprise a child of under 10 years old (claim 15).

Determination of the scope and content of the prior art

(MPEP 2141.01)

Quigley et al. teach a lotion composition comprising an antifungal, a low-mid strength steroidal anti-inflammatory (0.01 to 0.1 wt.% betamethasone dipropionate lotion), and excipients that don't afford steroidal penetration of the epidermis, as discussed above. Quigley et al. also teach a cream formulation comprising the same excipients as listed in the aforementioned lotion, wherein the steroid is preferably from 0.01 to 0.1 wt.%, and is preferably betamethasone dipropionate (column 7, line 38 through column 8, line 28; Table A).

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Quigley et al. do not explicitly teach an explicit composition comprising a low to low-medium potency steroidal anti-inflammatory having a structure shown in instant claim 2, nor those selected from the group listed in claim 7. However, Quigley et al. teach desonide cream 0.05% as a suitable steroid anti-inflammatory for use in the present invention (column 5, line 45). Desonide is a species within the generic structure of steroid anti-inflammatory compounds shown in instant claim 2 (instant claims 2-5).

Also, Quigley et al. do not explicitly teach applying the composition two times per day to the affected area. However, Quigley et al. teach that routine experimentation by one of ordinary skill in the art would be able to determine the effective amount of application of the topical composition (column 7, lines 11-24).

Furthermore, Quigley et al. do not teach applying the composition to a child of under 10 years old. However, Quigley et al. teach desonide cream 0.05% as a suitable steroidal anti-inflammatory and the instant specification teaches that desonide is a class 6 non-fluorinated topical corticosteroid which has been available for more than two decades and clinical trials have shown that desonide is effective and safe for treating children having dermatosis or other skin diseases.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to use desonide cream 0.05% in the cream formulation taught by Quigley et al. because Quigley et al. teach that desonide cream 0.05% is a suitable

steroidal anti-inflammatory for use in combination with an antifungal. One of ordinary skill in the art would have been motivated to use desonide cream 0.05% in the cream formulation of Quigley et al. because desonide is a class 6 non-fluorinated topical corticosteroid which has been available for more than two decades and clinical trials have shown that desonide is effective and safe for treating children having dermatosis or other skin diseases, as evidenced by the instant applications specification. Also, it would have been routine experimentation for a person of ordinary skill in the art to determine the number of applications of the cream formulation of Quigley et al. in order to achieve desired results in treating fungal diseases.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants argue on pages 11-12 that the only mention of desonide cream is in the table at col. 4-5, and thus there is not teaching to select desonide. However, the examiner respectfully argues that Quigley et al. teach a cream comprising 0.001-2.5 wt.% steroid anti-inflammatory selected from betamethasone, betamethasone dipropionate, fluocinonide, fluocinoline acetonide, hydrocortisone, methylprednisolone, clobetasol, and beclomethasone (Claims 1-7). Fluocinolone acetonide is a low-medium potency steroid as a cream at 0.025 wt.%, hydrocortisone is a low potency steroid at 2.5

wt.%, and methylprednisolone is a low potency steroid at 1 wt.%, according to the table on col. 4-5. Therefore, Quigley et al. clearly teach a cream composition comprising an antifungal and a steroidal anti-inflammatory where the steroidal anti-inflammatory is a low to low-medium potency steroid. Looking to the table at col. 4-5, desonide cream at 0.05 wt.% is the same potency as fluocinolone acetonide cream at 0.01 wt.%, hydrocortisone at 0.5, 1.0 and 2.5 wt.%, and methylprednisolone at 1 wt.% which are claimed by Quigley et al. at claim 7. Therefore, one of ordinary skill in the art would be motivated to look to the table at col. 4-5 to use steroid antiinflammatories that are interchangeable with those claimed in claim 7. Thus, one of ordinary skill would expect the use of desonide in a cream at 0.05 wt.% to behave the same as the composition as claimed in claim 7.

Applicants also argue that Quigley et al. teach away from the instant invention. However, the examiner addressed this argument above and thus the discussion above is incorporated herein by reference.

2. Claims 1-13 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Burnett et al. (US 6,238,683) in view of Shah et al. (US 5,219,877).

Applicant's claims

Applicant claims a topical antifungal composition comprising 0.1 to 5.0 wt.% clotrimazole, 0.01 to 5.0 wt.% desonide, and a carrier that does not afford penetration of the steroid through the skin causing undesirable side effects.

Determination of the scope and content of the prior art

(MPEP 2141.01)

Burnett et al. teach compositions comprising preferably about 0.05 wt.% desonide (col. 3, ll. 45-53) and preferably about 2 wt.% of an imidazole antifungal agent (col. 3, ll. 7-9 and 45-53), wherein the composition does not permeate through the skin, as discussed above.

Ascertainment of the difference between the prior art and the claims

(MPEP 2141.02)

Burnett et al. teach the antifungal agent includes ketoconazole, miconazole, itraconazole, metronidazole, elubiol, and like related imidazole antifungal agents known to those of skill in the art, but do not teach the antifungal agent to comprise clotrimazole as instantly claimed. However, Shah et al. teach formulations suitable for treatment of tinea capitis, tinea corporis, tinea cruris, and tinea pedis comprising 0.2 to 2.0% w/v of an imidazole antifungal agent, such as clotrimazole, and further comprising an anti-inflammatory steroid including desonide (column 1, lines 6-14; and column 3, lines 43-65). Shah et al. further teach that commercially marketed 1 wt.% clotrimazole exhibits very low permeation rates through skin, and cannot be effectively used for treatment of deep skin fungal infections (column 6, lines 3-34). Thus, the commercially marketed clotrimazole does not permeate through the skin.

Finding of *prima facie* obviousness

Rational and Motivation (MPEP 2142-43)

Therefore, it would have been *prima facie* obvious for one skilled in the art at the time of the invention to use clotrimazole as the imidazole antifungal agent in the

compositions of Burnett et al. because Shah et al. teach clotrimazole as a suitable imidazole antifungal for treating tinea capitis, tinea corporis, tinea cruris, and tinea pedis. One would have been motivated to use clotrimazole as the antifungal agent because Burnett et al. teaches the desire to reduce the amount of skin permeation in order to reduce side effects, and Shah et al. teach that commercially marketed 1 wt.% clotrimazole does not permeate through the skin.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Response to Arguments

Applicants argue on pages 13-14 that Shah et al. teach that mid-potency steroids are preferred, and that Shah et al. teach that low to low-medium potency steroids cause undesirable side effects and are not effective at providing relief from inflammation. However, the examiner respectfully argues that Shah et al. teach that strong fluorinated steroids cause undesirable effects and that low potency steroids fail to provide *fast* relief of inflammatory symptoms. Therefore, Shah et al. does not teach that low potency steroids are ineffective at providing relief from inflammation, but merely teach that they do not provide *fast* relief from inflammatory symptoms. Also, Shah et al. do not teach that low-medium potency steroids do not provide fast relief. Therefore, in combination with the teaching of Burnett et al. that compositions comprise desonide and preferably

about 2 wt.% of an imidazole antifungal agent, one would expect that using clotrimazole as the imidazole, as taught by Shah et al., would yield the same benefit as the imidazoles used in the compositions of Burnett et al.

Declaration under 37 CFR 1.132

The declaration under 37 CFR 1.132 filed 14 March 2007, which contains the same statements as the declaration filed 27 December 2005, states that prior art composition, Lotrisone, was a combination of anti-fungal clotrimazole with a high potency corticosteroid, betamethasone dipropionate. The declaration states that the steroid is too potent to be used safely on thin skinned areas of the body, and therefore, it would have been unethical to compare the compositions of the instant invention with compounds using stronger, more potent steroids, as there would be the real risk of major untoward side effects. The declaration further shows data wherein patients suffering from tinea cruris, intertriginous dermatitis, tinea corporis, tinea corporis with tinea pedis and onychomycosis, and inflammatory tinea were treated with clotrimazole 1% cream with alclometasone dipropionate 0.05% cream, oxicanozole cream 1% with hydrocortisone cream 2½%, econazole cream 1% with fluocinalone acetonide cream 0.01%, econazole cream 1% with alclometasone dipropionate 0.05% cream, and desonide cream with clotrimazole cream, respectively, wherein each patient had marked to complete clearing within several weeks.

As discussed above, Quigley et al. disclose in Table G a lotion comprising betamethasone dipropionate at 0.01 to 0.1 wt.% (a low-medium potency steroid at 0.02

wt.%). Quigley et al. further disclose that the compositions of their invention are useful for treating fungal diseases such as tinea pedis, tinea capitis, tinea corporis, tinea versicolor, scalp disorders, tinea cruris, and candidiasis (col. 7, ll. 25-30). Burnett et al. disclose a formulation comprising 2% ketoconazole and 0.05% desonide (a low or low-medium potency steroid) (Table 9), wherein the formulation is sufficient to treat tinea corporis, tinea cruris and tinea pedis (col. 7, ll. 14-18). The declaration does not overcome the rejections discussed above because there is not a side by side comparison of the compositions of the instant claims with the compositions of the closest prior art to indicate an unexpected result.

It is noted, as mentioned above, that Dr. Goldstein states that it would have been unethical to compare the compositions of the instant invention with compounds using stronger, more potent steroids, as there would be the real risk of major untoward side effects. However, the prior art clearly teaches compositions comprising low to low-medium potency steroids in combination with antifungal compounds (see Quigley et al. and Burnett et al., as discussed above). Therefore, in the absence of evidence to the contrary, the compositions and methods of the instant claims are anticipated and/or rendered obvious, as detailed above.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nathan W. Schlientz whose telephone number is 571-272-9924. The examiner can normally be reached on 8:30 AM to 5:00 PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NWS

/John Pak/
Primary Examiner, Art Unit 1616